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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/636,079	08/06/2003	Janet K. Yamamoto	UF-152FWCD2	1433

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	PAPER NUMBER
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/20/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/636,079	YAMAMOTO, JANET K.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-36,38-43,50,53-63,108 and 109* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31,33-36,50,55-62,108 and 109* is/are rejected.

7)☒ Claim(s) *32,38-43,53,54 and 63* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and response filed September 29, 2006 is acknowledged and entered. Claims 31-36, 38-43, 50, 53-63, 108 and 109 are pending and under examination.

Claim Rejections - 35 USC § 112

(*New Rejection*) Claims 33, 34, 59-62 and 109 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation of "said FIV virus or FIV-infected cell" in claims 33 and 34 lacks antecedent basis in claim 32. The recitation of "said FIV-infected cell" in claims 59-62 lacks antecedent basis in claim 32. The recitation of "said FIV envelope glycoprotein" in claim 109 lacks antecedent basis in claim 32.

Claims 31, 35, 36, 50, 55-58 and 108 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a vaccine composition that induces a protective immune response against two or more subtypes of FIV, comprising an effective amount of an FIV immunogen that minimally includes the FIV envelope glycoprotein, does not reasonably provide enablement for a vaccine comprising FIV peptides, proteins, and partial viruses that do not include the FIV envelope glycoprotein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims broadly encompass a vaccine composition that induces protection against FIV infection (of multiple subtypes), comprising an amount of any FIV immunogen. The

immunogens include synthetic FIV peptides, natural or recombinant FIV proteins, fragments of said proteins, cell-free whole or partial FIV virus, and cells infected with FIV virus. Applicant's specification is enabling for embodiments that encompass the FIV envelope glycoprotein from each of the at least two different FIV subtypes. Embodiments that do not encompass the envelope glycoprotein from each of the at least two difference subtypes, are not enabled by the specification.

The nature of the invention is the protection of felines against FIV infection by administering a composition that comprises at least two immunogens from at least two FIV subtypes. The state of the art is that dual subtype vaccines against FIV are effective when using embodiments that include the envelope proteins of both subtypes (*AIDScience*, 2002, Vol. 2, No. 8, pages 1-8, of record). The level of one of skill in the art is high, evidenced by the present inventors and those of the cited literature. The level of predictability in the art is limited when considering the administration of any FIV immunogen to protect against FIV. The level of predictability in the art with regard to embodiments that include envelope protein (such as whole virus, partial virus with envelope, and infected cell lines) increases. The amount of direction provided by the specification is limited to vaccines that include the envelope proteins of two subtypes. The working examples are drawn to infected cell lines that protect felines against FIV infection.

Given the breadth of the claims, the state of the art, the level of skill in the art, the level of predictability, the working examples, the direction provided by Applicant, and the nature of the invention, one of skill in the art would not be able to practice the full scope of the invention without undue experimentation. Since the only embodiments that have shown protective

capabilities are those that include the envelope protein of two subtypes, one of skill in the art would now know how to vaccinate with embodiments that do not include the envelope protein of two subtypes.

Applicant's arguments have been carefully considered but found unpersuasive. Applicant argues that the Office has not provided any basis to support the assertion that the subject specification is not enabled for compositions comprising immunogens other than the FIV envelope protein. Applicant notes that there is no requirement that Applicant test each and every possible embodiment encompassed within the scope of the claims in order to satisfy the enablement requirement. Applicant points to the specification, page 5 lines 6-7 and Example 2 of the specification for support of other embodiments for use in the instant application, such as cells infected with FIV. Applicant also points to numerous publications for support of their assertion that non-envelope proteins are capable of inducing an immune response against FIV, such as a protein encoded by the gag and pol genes of FIV.

In response to Applicant's arguments, the instant rejection acknowledges that immunogens that have the envelope protein are enabled. In other words, cells that contain FIV have the FIV envelope protein are enabled. However, partial FIV that does not contain envelope, non-envelope proteins and fragments thereof, for example, are not able to be used according to the instant claims drawn to vaccines. Only embodiments that encompass immunogens that have an FIV envelope protein are capable of inducing a protective immune response.

While Applicant argues that not every embodiment be tested, a representative number of embodiments are required to support the genus claimed. In this case, only one embodiment (immunogens that minimally contain an envelope protein) has been demonstrated as protective.

No other proteins have been shown to be responsible for the protective immune response induced. Vaccine efficacy requires challenge experiments. While challenge experiments have been conducted with FIV immunogens that minimally have an envelope protein, no experiments have been conducted with non-envelope proteins in the absence of envelope protein, or constructs comprising non-envelope proteins in the absence of envelope protein. Therefore, one cannot conclude that immunogens containing only non-envelope proteins are capable of inducing a protective immune response.

In response to Applicant's arguments, the Office has considered the cited references, which do not directly relate to the vaccine composition instantly claimed. US Patents 5,820,869 and 5,989,862 relate to recombinant poxvirus constructs that have DNA encoding the gag gene. US Patent 5,833,993 relates to DNA sequences encoding env and gag proteins. EPO Patent No. EP956360 relates to ALVAC vector constructs that have DNA encoding gag and protease, not protein-based vaccines, as instantly claimed. Coleman *et al.* (*AIDS* 2005, 19 :1457-1466) relates to the administration of human immunodeficiency virus p24 to felines to protect against feline immunodeficiency virus infection. None of these references relate to the instant claims that are drawn to protein vaccines comprised FIV immunogens for use against FIV infection. The data relating to poxvirus vector constructs is not directly analogous to protein vaccination given the differences in structure and mechanisms relied upon. The viral vector must be able to encode the proteins first, whereas the protein vaccine is already "expressing" the proteins. DNA vaccines induce different antibodies since the coding sequences are not translated into amino acids and polypeptides. Therefore, since the literature cited does not address the ability of FIV proteins vaccines that induce protection against FIV, the claims remain rejected for reasons of record.

Conclusion

Claims 32, 38-43, 53, 54 and 63 are free of the prior art and objected to for depending from rejected claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The

examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Stacy B Chen 12/5/06

STACY B. CHEN
PRIMARY EXAMINER